DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9 4339d

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

October 6, 2003

Ref: 2004-DAL-WL-02

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Warren B. Lee, President
Lee Pharmacy, Inc.
4300 Grand Ave.
Fort Smith, Arkansas 72904

Dear Dr. Lee:

This is regarding an inspection of your firm on December 11/13, 2002, by investigators of the U.S. Food and Drug Administration (FDA). The inspection was conducted pursuant to the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321 et, seq., as authorized by Inspection Warrant No. FS-02-38, signed by United States Magistrate Judge Beverly Stites Jones, and filed on December 10, 2002, in the United States District Court for the Western District of Arkansas, Fort Smith Division. The inspection disclosed serious violations of the Act.

We are in receipt of your post inspection written correspondence dated December 24 and 26, 2002, and January 8 and 24, and February 21, 2003. We acknowledge the changes you have indicated are being made to your compounded human drug products. However, we find your response regarding veterinary drugs to be unsatisfactory because you have made no statements indicating your corrective actions will ensure that prescription veterinary drugs are not compounded with the use of bulk active pharmaceutical ingredients (APIs).

Compounded Veterinary Drug Products:

Your firm compounds veterinary prescription injectable drug products, which are shipped to veterinary clinics for use in large and small animals, including food producing animals. The veterinary drugs compounded and distributed by your firm are adulterated under Section 501(a)(5) of the Act because they are unsafe within the meaning of Section 512 of the Act. Under Section 512, a new animal drug is deemed unsafe unless an approved New Animal Drug Application (NADA) is in effect for the specific product in question. None of the animal drugs compounded and distributed by your firm are the subject of an approved NADA.

The only legal compounding of animal drugs is provided under the Animal Medicinal Drug Use Clarification Act and its implementing regulations at 21 CFR Part 530, Extralabel Drug Use in Animals. Our investigation found that you did not comply with these requirements. For example, 21 CFR 530.13(a) requires that the compounding be conducted using approved animal or human drug products. However, your firm compounded with the use of bulk APIs, which is not permitted. Moreover, some of the veterinary products were compounded with the use of bulk drug substances, such as camphorated oil and cisapride, that have been withdrawn or removed from the market for human use for safety reasons. In addition, it appears the products were being compounded outside the context of a valid veterinarian-client-patient relationship, as required by 21 CFR 530.10(a), and that the scale of your compounding operation is not commensurate with the established need for the compounded products, as required by 21 CFR 530.13(b)(5).

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that all drug products compounded and processed by your firm are in compliance with federal laws and regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to seizure or injunction. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

Please notify this office within 15 working days of receipt of this letter of the additional specific steps you will take to correct these violations, including an explanation of each step being taken to prevent the recurrence of the violations. You should address your reply to this letter to the U. S. Food and Drug Administration, Attention: Jim Lahar, Compliance Officer, at the above letterhead address.

Compounded Human Drug Products - Methylprednisolone Acetate Injection and Triamcinolone Acetonide Injection:

In addition to the above serious violations, we also wish to advise you of FDA's analysis of Methylprednisolone Acetate Injection (a corticosteroid anti-inflammatory agent) that your pharmacy prepared on February 28, 2002, with Lot number 28022002:03, and "Use By" date of 02-03. Our laboratory analysis of this drug from an intact vial, confirmed the presence of *Penicillium rugulosum.* The drug sample, number 204499, was collected during an inspection of your firm on December 2, 2002, and represents a 3,000-mL lot/batch size.

This same lot was the subject of a Consumer Complaint (No. 15698). FDA collected two previously opened 10mL brown glass vials containing Methylprednisolone Acetate 40mg/ml P.F. from the complainant's clinic on November 25, 2002. Upon examination of the product, in the condition as received, mold was recovered from one of the two vials (sample number 118711). We acknowledge that you did recall all preservative free injectables compounded in year 2002, which included this lot.

FDA also collected a physical sample of Triamcinolone Acetonide 40mg/ml P.F. from batch 20062002:28 (sample number 169598). The 3,000-mL batch was compounded on June 20,2002, and had a "Use By" date of 06-03. The sample was tested for potency and was found to be sub-potent with aliquots from two sub-samples confirmed at 67.8% and 79.8% of label claim for potency.

The lot of Methylprednisolone Acetate Injection, which was recalled by your firm, violated Section 501(a)(1) of the Federal Food, Drug and Cosmetic Act (the Act), in that it consisted in whole or in part of a filthy, putrid, or decomposed substance. The lot of Triamcinolone Acetonide Injection, which has expired, violated Section 501(c) as labeled, or 501(b) if it is a suspension product (as the label and formulation imply), in that the strength differs from that which it purports or is represented to possess.

If you have any questions about the content of this letter, please contact Mr. Lahar at (214) 253-5219.

Sincerely,

Michael A. Chappell
District Director

MAC:JRL